EXHIBIT A

I

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

16-3725 BLS

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No.

CLASS ACTION

JURY TRIAL DEMANDED

SUFFOLK SUPERIOR COURT
CIVIL CLERK'S OFFICE
2016 DEC -5 P 1:29
MICHAEL JOSEPH DONOVAN
CLERK/MAGISTRATE

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***."[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to ***170*** metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

			Results				
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**
Xtandi	31	38% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago).*** M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price***.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

HUTCHINGS BARSAMIAN MANDELCORN, LLP
THEODORE M. HESS-MAHAN, BBO #557109

THEODORE M. HESS-MAHAN

110 Cedar Street, Suite 250
Wellesley Hills, MA 02481
Telephone: 781/431-2231
781/431-8726 (fax)
thess-mahan@hutchingsbarsamian.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
MARY K. BLASY
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631/367-1173 (fax)
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ROBBINS GELLER RUDMAN
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JAMES I. JACONETTE
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San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)
jjaconette@rgrdlaw.com

HOLZER & HOLZER, LLC
COREY D. HOLZER
MARSHALL DEES
1200 Ashford Parkway, Suite 410
Atlanta, GA 30338
Telephone: 770/392-0090
770/392-0029 (fax)
cholzer@holzerlaw.com
mdees@holzerlaw.com

Attorneys for Plaintiff

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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: TOKAI PHARMACEUTICALS, INC.

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.

1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED
   (1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on _____,201___, I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

_____

_____

_____

Dated:_____,201_____. _____

N.B. TO PROCESS SERVER: –
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
(AFFIX FILING STAMP HERE)

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: TMOTHY J. BARBERICH

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

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(Mass. R. Civ. P. 4)

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_____

_____

_____

Dated:_____,201___ _____

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: JODIE P. MORRISON

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)

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_____

_____

Dated:_____,201___ _____

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: LEE H. KALOWSKI

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)

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Dated: _____, 201___

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N.B. TO PROCESS SERVER:–
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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: DAVID A. KESSLER

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)

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_____

_____

Dated:_____,201___ _____

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: SETH L. HARRISON

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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_____

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: JOSEPH A. YANCHIK, III

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December, in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

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Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
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_____

_____

_____

Dated:_____,201___

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT OF THE TRIAL COURT

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No.

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***."[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to ***170*** metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

			Results				
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**
Xtandi	31	38% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago)***. M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price***.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

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CIVIL ACTION COVER SHEET	DOCKET NO(S) B.L.S.	Trial Court Of Massachusetts Superior Court Department County: SUFFOLK
PLAINTIFF(S) HAO WU, Individually and on Behalf of All Others Similarly Situated		DEFENDANT(S) TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC
ATTORNEY, FIRM NAME, ADDRESS AND TELEPHONE Board of Bar Overseers number Theodore M. Hess-Mahan (BBO #557109) Hutchings Barsamian Mandelcorn, LLP 110 Cedar Street, Suite 250, Wellesley Hills, MA 02481 (781) 431-2231		ATTORNEY (if known)

Origin Code Original Complaint

TYPE OF ACTION AND TRACK DESIGNATION (See reverse side) CODE NO. TYPE OF ACTION (specify) TRACK IS THIS A JURY CASE?
Securities Act of 1933 (B) (X) Yes ( ) No

The following is a full and detailed statement of the facts on which plaintiff relies to determine eligibility in to The Business Litigation Session.

This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

Plaintiff alleges that the Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein. Defendants are liable to plaintiff and the Class for the alleged misstatements and omission in the Registration for the IPO. Plaintiff seeks compensatory and/or rescissory damages on behalf of the Class.

The claims alleged herein arise under sections 11, 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§77k and 77o.

* A Special Tracking Order shall be created by the Presiding Justice of the Business Litigation Session at the Rule 16 Conference.

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT.

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods." Signature of Attorney of Record

DATE: 12/5/2016

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: **SUCV2016-03725-BLS2**

Case: Wu v. Tokai Pharmaceuticals, Inc. et al.

NOTICE OF ACCEPTANCE INTO BUSINESS LITIGATION SESSION

This matter has been accepted into the Suffolk Business Litigation Session. It has been assigned to **BLS2.**

Hereafter, as shown above, all parties must include the initials "**BLS2**" at the end of the docket number on all filings.

Counsel for the plaintiff(s) is hereby advised that within seven (7) days of the filing of an appearance, answer, motion or other response to the complaint by or on behalf of the defendant(s) which has been served with process within the time limitation of Mass. R. Civ. P. 4(j), or such other time as may be modified by the Court, he or she shall send notice thereof to the appropriate BLS Session Clerk at Suffolk Superior Court, Three Pemberton Square, Boston, MA 02108.

Upon receipt of such notice, the Court will issue a Notice of Initial Rule 16 Conference for purposes of meeting with all counsel. Before the Rule 16 Conference, counsel shall discuss with their clients and with opposing counsel whether the parties will participate in the BLS Pilot Project on Discovery (counsel are directed to http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html for description of the Project). Counsel may indicate their respective client's participation by completing, filing and serving the attached form. If by the date of the initial Rule 16 Conference, not all parties have given notice of their participation, counsel shall be prepared to discuss at that conference whether their clients will participate in the Pilot Project.

The Court requests that plaintiff's counsel serve on opposing parties a copy of this notice and the attached form.

Dated: 12/6/16
notice sent
12.06.16
TMH-M
HBM+RLP
(mw)

Janet L. Sanders
Justice of the Superior Court &
Administrative Justice of the Business Litigation Session

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: _____

Case: _____

As you may know, the Business Litigation Session began implementing a Discovery Project in January, 2010. This project is available on a voluntary basis for all new cases accepted into the BLS and for cases which have not previously had an initial case management conference. Counsel should be prepared to discuss the project with the Court at the initial case management conference. For a detailed copy of the BLS Discovery Project, counsel are directed to the Trial Court home page at: http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html)

If a party is willing to participate in the project, that party's counsel should so indicate below and return this form to the appropriate session clerk.

☐ **Yes**, _____ is willing to participate in the Discovery Project.
(Party's Name)

Case Name _____

Docket Number CIVIL DOCKET#: _____

Counsel For_____ Date_____

Firm Name and Address:

_____

_____

_____

Please complete this form and return it to:

Helen Foley, Asst. Clerk
BLS1, Room 1309
3 Pemberton Square
Boston, MA 02108

OR

Richard V. Muscato, Jr., Asst. Clerk
BLS2, Room 1017
3 Pemberton Square
Boston, MA 02108

Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

V.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: BMO CAPITAL MARKETS CORP.

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481, an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant, Esquire, at Boston, the ninth day of December, in the year of our Lord two thousand sixteen.

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.

1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED
   (1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

FORM CIV.P. 1 3rd Rev. 20M-10/11

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on _____,201___, I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

_____

_____

_____

Dated:_____,201____ _____

N.B. **TO PROCESS SERVER: –**
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

DECEMBER 13, 2016.

Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU , Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. , Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
(AFFIX FILING STAMP HERE)

Norfolk 12/16

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: **SUCV2016-03725-BLS2**

Case: Wu v. Tokai Pharmaceuticals, Inc. et al.

NOTICE OF ACCEPTANCE INTO BUSINESS LITIGATION SESSION

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Counsel for the plaintiff(s) is hereby advised that within seven (7) days of the filing of an appearance, answer, motion or other response to the complaint by or on behalf of the defendant(s) which has been served with process within the time limitation of Mass. R. Civ. P. 4(j), or such other time as may be modified by the Court, he or she shall send notice thereof to the appropriate BLS Session Clerk at Suffolk Superior Court, Three Pemberton Square, Boston, MA 02108.

Upon receipt of such notice, the Court will issue a Notice of Initial Rule 16 Conference for purposes of meeting with all counsel. Before the Rule 16 Conference, counsel shall discuss with their clients and with opposing counsel whether the parties will participate in the BLS Pilot Project on Discovery (counsel are directed to http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html for description of the Project). Counsel may indicate their respective client's participation by completing, filing and serving the attached form. If by the date of the initial Rule 16 Conference, not all parties have given notice of their participation, counsel shall be prepared to discuss at that conference whether their clients will participate in the Pilot Project.

The Court requests that plaintiff's counsel serve on opposing parties a copy of this notice and the attached form.

Dated: 12/6/16
notice sent
12.06.16
TMH-M
HBM-RLP
(MJ)

Janet L. Sanders
Justice of the Superior Court &
Administrative Justice of the Business Litigation Session

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: _____

Case: _____

As you may know, the Business Litigation Session began implementing a Discovery Project in January, 2010. This project is available on a voluntary basis for all new cases accepted into the BLS and for cases which have not previously had an initial case management conference. Counsel should be prepared to discuss the project with the Court at the initial case management conference. For a detailed copy of the BLS Discovery Project, counsel are directed to the Trial Court home page at: http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html)

If a party is willing to participate in the project, that party's counsel should so indicate below and return this form to the appropriate session clerk.

☐ Yes, _____ is willing to participate in the Discovery Project.
(Party's Name)

Case Name _____

Docket Number CIVIL DOCKET#: _____

Counsel For _____ Date _____

Firm Name and Address:

_____

_____

_____

Please complete this form and return it to:

Helen Foley, Asst. Clerk
BLS1, Room 1309
3 Pemberton Square
Boston, MA 02108

OR

Richard V. Muscato, Jr., Asst. Clerk
BLS2, Room 1017
3 Pemberton Square
Boston, MA 02108

FILE COPY

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

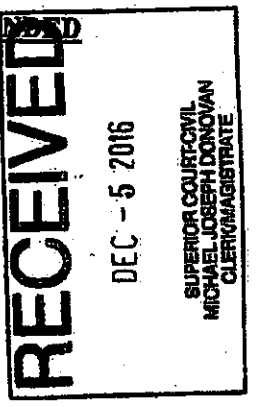
TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No. SUCV2016-03725-BLS2

CLASS ACTION

JURY TRIAL DEMANDED



CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement.***"[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to ***170*** metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

Treatment	N	AR-V7+	Results				
			AR-V7 Status	PSA50	P-value*	rPFS	P-value*
Xtandi	31	38% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago).*** M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price.***

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

HUTCHINGS BARSAMIAN MANDELCORN, LLP
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Attorneys for Plaintiff

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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

V.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: JANNEY MONTGOMERY SCOTT LLC

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq.
Hutchings Barsamian Mandelcorn, LLP
plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.
1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED
(1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

FORM CIV.P. 1 3rd Rev. 20M-10/11

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on _____, 201___, I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

_____

_____

_____

Dated: _____, 201___ _____

N.B. TO PROCESS SERVER: –
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

DECEMBER 13, 2016.

Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU, Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL., Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
(AFFIX FILING STAMP HERE)

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: SUCV2016-03725-BLS2

Case: Wu v. Tokai Pharmaceuticals, Inc. et al.

NOTICE OF ACCEPTANCE INTO BUSINESS LITIGATION SESSION

This matter has been accepted into the Suffolk Business Litigation Session. It has been assigned to **BLS2**.

Hereafter, as shown above, all parties must include the initials "BLS2" at the end of the docket number on all filings.

Counsel for the plaintiff(s) is hereby advised that within seven (7) days of the filing of an appearance, answer, motion or other response to the complaint by or on behalf of the defendant(s) which has been served with process within the time limitation of Mass. R. Civ. P. 4(j), or such other time as may be modified by the Court, he or she shall send notice thereof to the appropriate BLS Session Clerk at Suffolk Superior Court, Three Pemberton Square, Boston, MA 02108.

Upon receipt of such notice, the Court will issue a Notice of Initial Rule 16 Conference for purposes of meeting with all counsel. Before the Rule 16 Conference, counsel shall discuss with their clients and with opposing counsel whether the parties will participate in the BLS Pilot Project on Discovery (counsel are directed to http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html for description of the Project). Counsel may indicate their respective client's participation by completing, filing and serving the attached form. If by the date of the initial Rule 16 Conference, not all parties have given notice of their participation, counsel shall be prepared to discuss at that conference whether their clients will participate in the Pilot Project.

The Court requests that plaintiff's counsel serve on opposing parties a copy of this notice and the attached form.

Dated: 12/6/16
Notice sent
12.06.16
TMH-M
HBMT RLP
(MJ)

Janet L. Sanders
Justice of the Superior Court &
Administrative Justice of the Business Litigation Session

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: _____

Case: _____

As you may know, the Business Litigation Session began implementing a Discovery Project in January, 2010. This project is available on a voluntary basis for all new cases accepted into the BLS and for cases which have not previously had an initial case management conference. Counsel should be prepared to discuss the project with the Court at the initial case management conference. For a detailed copy of the BLS Discovery Project, counsel are directed to the Trial Court home page at: http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html)

If a party is willing to participate in the project, that party's counsel should so indicate below and return this form to the appropriate session clerk.

☐ Yes, _____ is willing to participate in the Discovery Project.
(Party's Name)

Case Name _____

Docket Number CIVIL DOCKET#: _____

Counsel For _____ Date _____

Firm Name and Address:

_____

_____

_____

Please complete this form and return it to:

Helen Foley, Asst. Clerk
BLS1, Room 1309
3 Pemberton Square
Boston, MA 02108

OR

Richard V. Muscato, Jr., Asst. Clerk
BLS2, Room 1017
3 Pemberton Square
Boston, MA 02108

FILE COPY

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

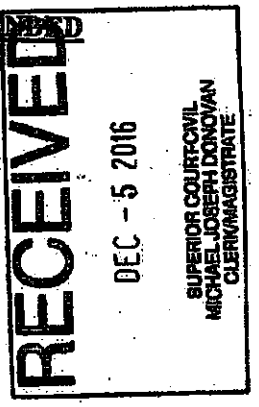
TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No. SUCV2016-03725-BLS2

CLASS ACTION

JURY TRIAL DEMANDED



CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement.***"[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to ***170*** metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

Treatment	N	AR-V7+	Results				
			AR-V7 Status	PSA50	P-value*	rPFS	P-value*
Xtandi	31	36% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	31.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago).*** M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price.***

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

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Attorneys for Plaintiff

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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

V.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: STIFEL, NICOLAUS & COMPANY, INCORPORATED

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481 , an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant , Esquire, at Boston, the ninth day of December , in the year of our Lord two thousand sixteen .

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.

1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED

(1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on _____,201___, I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

_____

_____

_____

Dated:_____,201____ _____

N.B. TO PROCESS SERVER: –
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

DECEMBER 13 ,2016.

Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU _____, Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL. _____, Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
(AFFIX FILING STAMP HERE)

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: SUCV2016-03725-BLS2

Case: Wu v. Tokai Pharmaceuticals, Inc. et al.

NOTICE OF ACCEPTANCE INTO BUSINESS LITIGATION SESSION

This matter has been accepted into the Suffolk Business Litigation Session. It has been assigned to **BLS2.**

Hereafter, as shown above, all parties must include the initials "BLS2" at the end of the docket number on all filings.

Counsel for the plaintiff(s) is hereby advised that within seven (7) days of the filing of an appearance, answer, motion or other response to the complaint by or on behalf of the defendant(s) which has been served with process within the time limitation of Mass. R. Civ. P. 4(j), or such other time as may be modified by the Court, he or she shall send notice thereof to the appropriate BLS Session Clerk at Suffolk Superior Court, Three Pemberton Square, Boston, MA 02108.

Upon receipt of such notice, the Court will issue a Notice of Initial Rule 16 Conference for purposes of meeting with all counsel. Before the Rule 16 Conference, counsel shall discuss with their clients and with opposing counsel whether the parties will participate in the BLS Pilot Project on Discovery (counsel are directed to http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html for description of the Project). Counsel may indicate their respective client's participation by completing, filing and serving the attached form. If by the date of the initial Rule 16 Conference, not all parties have given notice of their participation, counsel shall be prepared to discuss at that conference whether their clients will participate in the Pilot Project.

The Court requests that plaintiff's counsel serve on opposing parties a copy of this notice and the attached form.

Dated: 12/6/16
notice sent
12.06.16
TMH-M
HBM-RLP
(MJ)

Janet L. Sanders
Justice of the Superior Court &
Administrative Justice of the Business Litigation Session

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: _____

Case: _____

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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No. SUCV2016-03725-BLS2

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***."[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to *170* metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

			Results				
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**
Xtandi	31	38% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago).*** M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price.***

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

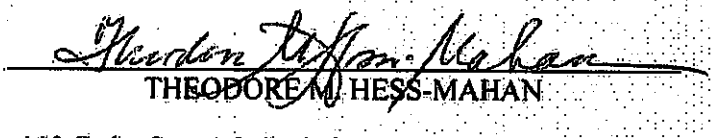
E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

HUTCHINGS BARSAMIAN MANDELCORN, LLP
THEODORE M. HESS-MAHAN, BBO #557109



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Attorneys for Plaintiff

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Commonwealth of Massachusetts

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION

No. SUCV2016-03725-BLS2

HAO WU , Plaintiff(s)

V.

TOKAI PHARMACEUTICALS, INC., ET AL. , Defendant(s)

SUMMONS

To the above-named Defendant: WILIAM BLAIR & COMPANY, L.L.C.

You are hereby summoned and required to serve upon Theodore M. Hess-Mahan, Esq. Hutchings Barsamian Mandelcorn, LLP plaintiff's attorney, whose address is 110 Cedar Street, Wellesley, MA 02481, an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Boston either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Judith Fabricant, Esquire, at Boston, the ninth day of December, in the year of our Lord two thousand sixteen.

Michael Joseph Donovan

Clerk/Magistrate

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

NOTES.

1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.
3. TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED

(1) TORT — (2) MOTOR VEHICLE TORT — (3) CONTRACT — (4) EQUITABLE RELIEF — (5) OTHER

FORM CIV.P. 1 3rd Rev. 20M-10/11

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on _____, 201___, I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

_____

_____

_____

Dated: _____, 201___ _____

N.B. TO PROCESS SERVER: –
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

DECEMBER 13, 2016.

Commonwealth of Massachusetts

SUFFOLK, ss. SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION
No. SUCV2016-03725-BLS2

HAO WU, Plff(s).

v.

TOKAI PHARMACEUTICALS, INC., ET AL., Deft(s).

SUMMONS
(Mass. R. Civ. P. 4)
(AFFIX FILING STAMP HERE)

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: SUCV2016-03725-BLS2

Case: Wu v. Tokai Pharmaceuticals, Inc. et al.

NOTICE OF ACCEPTANCE INTO BUSINESS LITIGATION SESSION

This matter has been accepted into the Suffolk Business Litigation Session. It has been assigned to **BLS2.**

Hereafter, as shown above, all parties must include the initials "BLS2" at the end of the docket number on all filings.

Counsel for the plaintiff(s) is hereby advised that within seven (7) days of the filing of an appearance, answer, motion or other response to the complaint by or on behalf of the defendant(s) which has been served with process within the time limitation of Mass. R. Civ. P. 4(j), or such other time as may be modified by the Court, he or she shall send notice thereof to the appropriate BLS Session Clerk at Suffolk Superior Court, Three Pemberton Square, Boston, MA 02108.

Upon receipt of such notice, the Court will issue a Notice of Initial Rule 16 Conference for purposes of meeting with all counsel. Before the Rule 16 Conference, counsel shall discuss with their clients and with opposing counsel whether the parties will participate in the BLS Pilot Project on Discovery (counsel are directed to http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html for description of the Project). Counsel may indicate their respective client's participation by completing, filing and serving the attached form. If by the date of the initial Rule 16 Conference, not all parties have given notice of their participation, counsel shall be prepared to discuss at that conference whether their clients will participate in the Pilot Project.

The Court requests that plaintiff's counsel serve on opposing parties a copy of this notice and the attached form.

Dated: 12/6/16
notice sent
12.06.16
TMHM
HBMTRLP
(mw)

Janet L. Sanders
Justice of the Superior Court &
Administrative Justice of the Business Litigation Session

Commonwealth of Massachusetts
County of Suffolk
The Superior Court

CIVIL DOCKET#: _____

Case: _____

As you may know, the Business Litigation Session began implementing a Discovery Project in January, 2010. This project is available on a voluntary basis for all new cases accepted into the BLS and for cases which have not previously had an initial case management conference. Counsel should be prepared to discuss the project with the Court at the initial case management conference. For a detailed copy of the BLS Discovery Project, counsel are directed to the Trial Court home page at: http://www.mass.gov/courts/court-info/trial-court/sc/sc-bls-gen.html)

If a party is willing to participate in the project, that party's counsel should so indicate below and return this form to the appropriate session clerk.

☐ Yes, _____ is willing to participate in the Discovery Project.
(Party's Name)

Case Name _____

Docket Number CIVIL DOCKET#: _____

Counsel For _____ Date _____

Firm Name and Address:

_____

_____

_____

Please complete this form and return it to:

Helen Foley, Asst. Clerk
BLS1, Room 1309
3 Pemberton Square
Boston, MA 02108

OR

Richard V. Muscato, Jr., Asst. Clerk
BLS2, Room 1017
3 Pemberton Square
Boston, MA 02108

FILE COPY

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

HAO WU, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

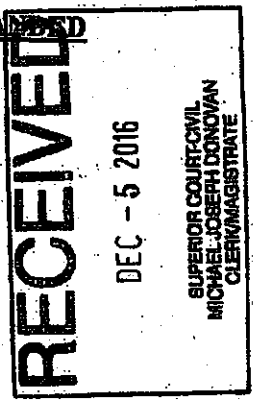
TOKAI PHARMACEUTICALS, INC., JODIE P. MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BARBERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C. and JANNEY MONTGOMERY SCOTT LLC,

Defendants.

Civil Action No. SUCV2016-03725-BLS2

CLASS ACTION

JURY TRIAL DEMANDED



CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SECURITIES ACT OF 1933

Plaintiff Hao Wu ("plaintiff") alleges the following based upon the investigation of plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company"), as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Tokai pursuant and/or traceable to the Registration Statement and Prospectus issued in connection

with Tokai's September 18, 2014 initial public stock offering (the "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "Securities Act").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to Mass. Gen. Law ("M.G.L.") ch. 212, §3. This action is not removable. The claims alleged herein arise under §§11, 12(a)(2) and 15 of the Securities Act. *See* 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the Securities Act. Section 22 of the Securities Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this title and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of "covered class action" under §16(b)-(c) and therefore is not removable to federal court. *See Carlson v. OvaScience, Inc.*, No. 15-14032-WGY, 2016 U.S. Dist. LEXIS 67617 (D. Mass. May 23, 2016); *Fortunato v. Akebia Therapeutics, Inc.*, No. 15-13501-PBS, 2016 U.S. Dist. LEXIS 57365 (D. Mass. Apr. 29, 2016); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 322 F. Supp. 2d 116 (D.N.H. 2004); *see generally Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 767-68 (1st Cir. 2011) (as "section 22 of the Securities Act, 15 U.S.C. §77v(a)" provides that "'no case arising under [the Securities Act] and brought in any State court of competent jurisdiction shall be removed to any court of the United States,'" plaintiffs have a "right to insist on non-removal" of such claim brought in state court); *Luther v. Countrywide Home Loans Servicing LP*, 533 F.3d 1031, 1032 (9th Cir. 2008) ("Section 22(a) of the Securities Act of 1933 creates concurrent jurisdiction in state and federal courts over claims arising under the Act. It also specifically provides that such claims brought in state court are not subject to removal to federal court.").

3. Personal jurisdiction is conferred by M.G.L. ch. 223, §37 and M.G.L. ch. 223A, §3 in that defendants have transacted business and committed acts directly relating to matters complained herein within the State of Massachusetts. This Court has personal jurisdiction over each of the

defendants named herein because they conducted business in and/or were citizens of Massachusetts at the time of the IPO. Tokai is headquartered in Boston. The Boston office of Wilmer Cutler Pickering Hale and Dorr LLP represented the Company in the IPO and the Boston office of Goodwin Procter LLP represented the Underwriter Defendants (as defined below) in the IPO. Each of the Underwriter Defendants has offices in and/or conducts significant business in Boston as well. The violations of law complained of herein also occurred in Boston, including the preparation and dissemination of the materially false and misleading Registration Statement complained of herein, which statements were disseminated into this state.

4. Venue is proper in Suffolk County pursuant to §22 of the Securities Act and M.G.L. ch. 223, §1, because defendants have locations, are advertising and doing business within Suffolk County and because many of the transactions or parts thereof as alleged herein occurred within Suffolk County, and defendants' wrongful acts arose in and emanated from this County. Tokai's executive headquarters are located at 255 State Street, Boston, Massachusetts. Individual Defendant Barberich (defined below) resides in Suffolk County, and each of the other Individual Defendants, including defendants Morrison and Yanchik who reside in the Massachusetts county of Middlesex, undertook activities related to the IPO from Tokai's Suffolk County headquarters.

5. This matter is properly before the Suffolk County Business Litigation Sessions pursuant to Superior Court Administrative Directive 09-1, subparts a.3, as these claims relate "to liability of . . . directors" and "officers" of Tokai; b.2, as these claims relate "to or aris[e] out of securities transactions"; c.1, as these "claims involv[e] . . . issuance of . . . equity"; and g.1, as these "claims aris[e] from transactions with . . . investment bankers."

PARTIES

6. Plaintiff Hao Wu purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby.

7. Defendant Tokai is a biopharmaceutical company focused on developing and commercializing therapies for prostate cancer and other hormonally driven diseases.

8. Defendant Jodie P. Morrison ("Morrison") is, and was at the time of the IPO, the President and Chief Executive Officer ("CEO") of Tokai.

9. Defendant Lee H. Kalowski was, at the time of the IPO, the Chief Financial Officer of Tokai.

10. Defendants Seth L. Harrison ("Harrison") and Joseph A. Yanchik, III ("Yanchik") co-founded Tokai in 2004 and served at the time of its IPO and continue to serve as members of its Board of Directors, with defendant Harrison serving as the Chairman of the Board.

11. Defendants Timothy J. Barberich ("Barberich") and David A. Kessler were both, at the time of the IPO, members of the Tokai Board of Directors.

12. The defendants named in ¶¶8-11 are referred to herein as the "Individual Defendants." The Individual Defendants each signed the Registration Statement.

13. Defendants BMO Capital Markets Corp. ("BMO"), Stifel, Nicolaus & Company, Incorporated, William Blair & Company, L.L.C. ("William Blair") and Janney Montgomery Scott LLC ("Janney") are financial services companies that acted as underwriters of Tokai's IPO, helping to draft and disseminate the offering documents, and are referred to herein as the "Underwriter Defendants." Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that specialize, *inter alia*, in underwriting public offerings of securities. They served as the underwriters of the IPO and shared more than $7.3 million in fees collectively. The Underwriter Defendants determined that in return for their share of the IPO proceeds they were willing to merchandize Tokai stock in the IPO. The Underwriter Defendants arranged a multi-city roadshow prior to the IPO during which they, and representatives from Tokai, met with potential investors and presented highly favorable information about the Company, its operation and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Tokai that Tokai would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws. They also made certain that Tokai had purchased millions of dollars in directors' and officers' liability insurance.

(c) Representatives of the Underwriter Defendants also assisted Tokai and the Individual Defendants in planning the IPO and purportedly conducted an adequate and reasonable

investigation into the business and operations of Tokai, an undertaking known as a "due diligence" investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their "due diligence," the Underwriter Defendants had continual access to confidential corporate information concerning Tokai's operations and financial prospects.

(d) In addition to availing themselves of virtually unbridled access to internal corporate documents, agents of the Underwriter Defendants met with Tokai's lawyers, management and top executives and engaged in "drafting sessions" between at least May 2014 and September 2014. During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Tokai stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures about Tokai would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Tokai management and top executives, the Underwriter Defendants knew, or should have known, of Tokai's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with offers and sales thereof, including to plaintiff and the Class.

SUBSTANTIVE ALLEGATIONS

14. Defendant Tokai is a biopharmaceutical company founded in 2004 by defendants Harrison and Yanchik.

15. At the time of its IPO, the Company had a single drug under development, galeterone, which it was developing for the treatment of prostate cancer for a very specific "subgroup of a subgroup" of patients for whom existing treatments were not effective. Specifically, galeterone was designed to target patients with metastatic castration-resistant prostate cancer ("CRPC") that expressed a particular genetic mutation. Throughout her tenure at Tokai, defendant Morrison, Tokai's CEO, has led the Company's galeterone prostate cancer development program.

16. There are only two drugs approved by the U.S. Food and Drug Administration ("FDA") for the treatment of CRPC, xtandi offered by Medivation and zytiga offered by Johnson & Johnson. Together, these two drugs were bringing in over $3 billion in annual revenues prior to the IPO. However, neither xtandi nor zytiga demonstrated effectiveness in treating CRPC patients with the truncated androgen receptor known as AR-V7 that Tokai claimed to be able to treat with galeterone. If approved, the annual galeterone market was estimated to be $500 million to $1 billion.

The FDA Drug Testing and Approval Process

17. The FDA regulates the sale and marketing of pharmaceutical products. The FDA reviews new drugs through New Drug Applications ("NDA"). The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. Clinical trials have three phases – I, II and III – which must be successfully completed before submission of an NDA to the FDA. Phase III clinical trials are the last and most important phase of testing and if successful significantly advance a developmental drug's prospects for FDA consideration and approval.

18. The development and marketing approval process for a new drug has several phases:

(a) Clinical Trials, Phase I – In this phase, a small, controlled trial involving human subjects is conducted to study the drug's safety profile, including the safe dosage range. Phase I studies also determine how a drug is absorbed, distributed and metabolized, as well as the duration of its action.

(b) Clinical Trials, Phase II – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(c) Clinical Trials, Phase III – This phase usually involves a large number of patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

(d) NDA Submission and Review – This phase begins with a threshold review of the Phase III clinical trial data and completeness of the application for substantive review. Once the NDA is accepted for filing, an FDA disciplinary review is commenced to determine if clinical trial

and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks.

19. When Tokai commenced its Phase II clinical trial of galeterone in 2012, rather than testing galeterone for the treatment of AR-V7 patients, the Company tested galeterone on all CRPC patients. The study evaluated 87 patients who were specifically classified as CRPC. The data included 17 patients who were non-metastatic and treatment naïve (no other drugs given) and 39 patients who were metastatic and treatment naïve. It also included 26 patients who had received zytiga and 5 who had received xtandi.

20. In preparation for its IPO, Tokai sought to differentiate its offering from those of xtandi and zytiga by cherry-picking from its Phase II clinical data, on an *ad hoc* basis, the data from a few patients who were classified as AR-V7 and in whom galeterone proved effective. The Company's sole rationale for taking galeterone into Phase III clinical trials based on this scant, cherry-picked Phase II data was its own after-the-fact "retrospective subset analysis" of the Phase II data, which Tokai claimed demonstrated positive results in six of the 87 test subjects. Specifically, the Company deduced that six of the Phase II clinical patients "showed clinically meaningful PSA reductions of at least 50%."

21. Moreover, when Tokai met with the FDA in August 2014 concerning the design of the Phase III clinical trial it sought to launch (dubbed "ARMOR3-SV"), the FDA staff explicitly advised Tokai that based on the unique endpoint Tokai had selected for its sole Phase III clinical trial, the Phase III clinical data would need to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***."[1]

22. Essentially, Tokai ***both designed*** and commenced its Phase III clinical trial never having conducted a single clinical trial designed to meaningfully test the effectiveness of galeterone on AR-V7 patients specifically, nor had it run a comparative trial designed to test the drug's effectiveness versus zytiga or xtandi. Instead, the Company merely conducted its Phase II clinical trial testing galeterone for effectiveness in CRPC patients, and happened to stumble upon the

[1] All emphasis has been added unless otherwise noted.

findings concerning the purported "efficacy" in the AR-V7 patient subgroup in its efforts to differentiate its product offering for purposes of marketing its IPO.

The IPO Registration Statement and Prospectus

23. On May 2, 2014, Tokai filed with the SEC a Registration Statement on Form S-1, which would later be utilized for the IPO following several amendments in response to comments by the SEC. On September 16, 2014, the SEC declared the Registration Statement effective. On or about September 18, 2014, Tokai and the Underwriter Defendants priced the IPO, filed the final Prospectus for the IPO, which forms part of the Registration Statement (collectively, the "Registration Statement"), with the SEC, and commenced the IPO.

24. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

25. Concerning the Company's Phase III clinical trial of galeterone, the Registration Statement stated that the "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," that the "primary endpoint of the trial [would] be radiographic progression-free survival and the secondary endpoints of the trial [would] include reduction of PSA levels, overall survival and safety," and that Tokai "expect[ed] to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016." Specifically concerning the Company's design of its Phase III ARMOR3-SV trial, the Registration Statement stated that Tokai was "currently finalizing [its] plans for [the] pivotal Phase 3 clinical trial of galeterone based on discussions with the U.S. Food and Drug Administration, or FDA" and that it "anticipate[d] initiating the trial in the first half of 2015," without disclosing the full extent of the FDA's admonitions concerning the design of its Phase III clinical trial.

26. Specifically, concerning the design of the Company's Phase III clinical trial, while conceding that "[f]or drug and biological products, the FDA typically requires the successful

completion of two adequate and well-controlled clinical trials to support marketing approval" and that, "[i]n the case of galeterone, [Tokai] intend[ed] to seek approval based upon the results of a single pivotal clinical trial," the Registration Statement failed to disclose the material fact that the Company had not obtained meaningful clinical data from its Phase II clinical trial that would permit it to design a Phase III clinical trial that could demonstrate sufficient efficacy.

27. Concerning the clinical trial design, while the Registration Statement stated that Tokai's "ARMOR3-SV trial [would] be a randomized, open label clinical trial comparing galeterone to Xtandi in up to ***170*** metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant," it failed to disclose the material fact that this was a much smaller number of CRPC patients than the 1,199 and 1,195 patients who had been tested in the xtandi and zytiga Phase III clinical trials, respectively, meaning that the data derived in Tokai's Phase III clinical trial would not be clinically meaningful enough to demonstrate efficacy.

28. Concerning clinical trials conducted by researchers at Johns Hopkins University ("Johns Hopkins"), which the Registration Statement stated demonstrated that "the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion," "indicat[ing] that there [was] a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7," the Registration Statement explained, in relevant part, as follows:

> *Johns Hopkins*. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression-free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression-free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression-free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

			Results				
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**
Xtandi	31	35% (12/31)	+	0%	0.004	2.1 months	<0.001
			-	52%		6.1 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001
			-	68%		Not Reached	

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

29. However, in June 2016, at the American Society of Clinical Oncology annual meeting, the Johns Hopkins cohort data would be updated, which would narrow the point estimates on the assumptions for ARMOR3-SV, thereby lowering its probability of success. Specifically, as explained by Underwriter Defendant William Blair in its June 16, 2016 client note:

- ***Management discussed the updated data from the Johns Hopkins cohort presented at the American Society of Clinical Oncology (ASCO) annual meeting (June 3-7, Chicago).*** M1 patients harboring the AR-V7 variant treated with Xtandi or Zytiga had an rPFS of 4.1 months, and a PSA50 response (PSA drop of 50% or more from baseline) of 26% in this expanded cohort. This contrasts with data from the original cohort for which the rPFS

> was 2.1 months and PSA50 was 0%. The updated data narrows the point estimates on the assumptions for ARMOR3-SV. Previously, we were more comfortable with an 86% versus 0% PSA50 response difference between galeterone and Xtandi, and a 7.3-month versus 2.1-month difference in rPFS, both in AR-V7 positive patients. With the updated data, the PSA50 response is now 86% versus 26%, and rPFS became 7.3 months versus 4.1 months. The smaller magnitude of difference had lowered our confidence in the eventual success of ARMOR3-SV to 75% from 80%. Management commented that the ARMOR3-SV study is 90% powered to demonstrate an 82% improvement in rPFS for galeterone over Xtandi, and it assumed conservatively from the beginning that the Xtandi arm would have a 4-month rPFS, not 2 months. Further, the 7.3 months generated from the Phase II single-arm ARMOR2 study was time to PSA progression (TTTP). Since TTTP is generally 1-2 months shorter than rPFS, the rPFS for galeterone should be greater than 7.3 months and might be in the 8- to 9-month range. The updated data from the Johns Hopkins cohort eliminated some of the safety margin we previously thought to be there . . . .

30. Moreover, the Registration Statement overstated the Company's basis to claim that it had demonstrated galeterone's efficacy through its prior clinical trials. Specifically, the Registration Statement stated that Tokai "believe[d] that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provide[d] an opportunity to treat [a] population of patients" "with [CRPC] whose prostate tumor cells express an altered androgen receptor that is truncated." The Registration Statement also stated that in Tokai's "ongoing Phase 2 clinical trial of galeterone, . . . refer[red] to as [its] ARMOR2 trial, [the Company] observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven patients." The Registration Statement further stated that Tokai then "believe[d] that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments" then available, including xtandi and zytiga. However, Tokai had merely cherry-picked those seven patients with the AR-V7 variant from the 87 CRPC patients it initially began studying, ***after the fact***, in order to demonstrate a new and unique treatment compared to xtandi and zytiga, and in so doing had materially changed the Company's business plan in the eleventh hour. In addition, because the FDA had provided the Company with significant material

admonitions concerning the design of its Phase III clinical trial that the Registration Statement failed to disclose, the Registration Statement overstated the efficacy galeterone had yet demonstrated.

31. The statements referenced above in ¶¶23-30 were inaccurate statements of material fact because they failed to disclose the following material facts which existed at the time of the IPO:

(a) there was a patient imbalance in the galeterone to Xtandi arms of the Phase III clinical trial;

(b) the Johns Hopkins cohort data provided in the Registration Statement understated the response rate of xtandi and zytiga on treating patients with the AR-V7 variant, meaning that galeterone had to be even more efficacious to demonstrate superiority than the Registration Statement represented;

(c) because the Company had not obtained data that was meaningful enough from its Phase II clinical trial to be able to design a Phase III clinical trial that could demonstrate sufficient efficacy, the ARMOR3-SV trial was not designed to demonstrate clinical efficacy;

(d) the efficacy demonstrated in the Phase II clinical trial was overstated;

(e) because Tokai's Phase III clinical trial included only 170 patients, it was not designed to demonstrate "***a statistically persuasive large relative and absolute magnitude of improvement***" as to is unique endpoint as the FDA had expressly demanded at the August 2014 meeting;

(f) the Company's focus on seeking FDA approval for galeterone as a potential treatment for CRPC patients with the AR-V7 variant was the result of an eleventh-hour revision of the Company's business model in order to ferret out a unique use for the drug so the Company could claim to be on the path to obtaining FDA approval to market the drug; and

(g) as a result, the Company's business metrics and financial prospects were not as strong as indicated in the Registration Statement.

32. Under the rules and regulations governing the preparation of the Registration Statement, Tokai was required to disclose at the time of the IPO the defects in the design of it Phase III clinical trial, the FDA's significant admonitions provided in August 2014, and that the Registration Statement overstated the efficacy of galeterone as demonstrated through clinical trials.

The Registration Statement, however, contained no such disclosures. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303, and the SEC's related interpretive releases thereto, issuers are required to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. These adverse events and uncertainties were reasonably likely to have a material impact on Tokai's profitability, and, therefore, were required to be disclosed in the Registration Statement.

33. The IPO was successful for the Company and the Underwriter Defendants, who sold more than 7 million shares of Tokai common stock to the public at $15 per share, raising more than $105 million in gross proceeds.

34. After the IPO, the market learned of the significant defects in the Phase III clinical trial design and that Tokai was abandoning further development of galeterone because it had previously overstated its efficacy. As a result of these disclosures, at the time of the filing of this action, Tokai stock is trading at approximately $1 per share, ***a 92% decline from the IPO price.***

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Massachusetts Rules of Civil Procedure on behalf of a class consisting of all those who purchased Tokai common stock pursuant and/or traceable to the Registration Statement issued in connection with the IPO (the "Class"). Excluded from the Class are defendants and their families, the officers and directors and affiliates of defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether defendants violated the Securities Act;

(b) whether the Registration Statement was negligently prepared and contained inaccurate statements of material fact and omitted material information required to be stated therein; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CAUSE OF ACTION

For Violation of §11 of the Securities Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. This Cause of Action is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

43. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

44. Defendants are strictly liable to plaintiff and the Class for the misstatements and omissions.

45. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

46. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated, §11 of the Securities Act.

47. Plaintiff acquired Tokai common stock traceable to the IPO.

48. Plaintiff and the Class have sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to defendants' violations.

49. At the time of their purchases of Tokai common stock, plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that plaintiff commenced this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time plaintiff commenced this action.

SECOND CAUSE OF ACTION

For Violation of §12(a)(2) of the Securities Act Against All Defendants

50. Plaintiff incorporates ¶¶1-49 by reference.

51. By means of the defective Prospectus, defendants promoted and sold Tokai stock to plaintiff and other members of the Class. This is a non-fraud cause of action. Plaintiff does not assert that defendants committed intentional or reckless misconduct or that defendants acted with scienter or fraudulent intent.

52. The Prospectus contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above. Defendants owed plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

53. Plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus did not know, nor in the exercise of reasonable diligence could they have known, of the untruths and omissions contained in the Prospectus at the time they acquired Tokai common stock.

54. By reason of the conduct alleged herein, defendants violated §12(a)(2) of the Securities Act. As a direct and proximate result of such violations, plaintiff and the other members of the Class who purchased Tokai common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, plaintiff and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to defendants sued herein. Class members who have sold their common stock seek damages to the extent permitted by law.

THIRD CAUSE OF ACTION

For Violation of §15 of the Securities Act Against the Company and the Individual Defendants

55. Plaintiff incorporates ¶¶1-54 by reference.

56. This Cause of Action is brought pursuant to §15 of the Securities Act against the Company and the Individual Defendants.

57. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai. The Individual Defendants each had a series of

direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Tokai. The Company controlled the Individual Defendants and all of Tokai's employees.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying plaintiff as a Class representative under Massachusetts Rule of Civil Procedure 23 and appointing plaintiff's counsel Class Counsel;

B. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: December 5, 2016

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